CROMPTON | SEAGER | TUFTE | LLC
Patent, Trademark & Copyright Attorneys

1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Phone 612.677.9050
Fax 612.359.9349

FAX TRANSMISSION

DATE: November 8, 2004

TO: Commissioner for Patents
Attn: Examiner V. Bui
P.O. Box 1450
Alexandria, VA 22313-1450

FROM: David M. Crompton

OUR REF: 1001.1458101
TELEPHONE: 612-677-9050

Total pages, including cover letter: 25

PTO FAX NUMBER: 703-872-9306

If you do NOT receive all of the pages, please telephone us at (612) 677-9050, or fax us at (612) 359-9349.

Title of Document(s) Transmitted: APPEAL BRIEF UNDER 37 C.F.R. § 1.192
AMENDMENT UNDER 37 C.F.R. § 1.116(b)

Applicant: Henry J. Pepin
Serial No.: 09/898,687
Filed: July 3, 2001
Group Art Unit: 3731
Our Ref. No.: 1001.1458101
Confirmation No.: 1767
Customer No.: 28075

Please charge Deposit Account No. 50-0413 in the amount of $340.00, Fee Code 1402.
Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413. These papers are submitted on the first business day following a deadline which fell on a weekend; therefore no extension of time is due.

By: David M Crompton
Name: David M. Crompton
Reg. No. 36,772

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on the date shown below.

Kathleen L Boekley
Name: Kathleen L. Boekley

November 8, 2004
Date

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Henry J. Pepin	Confirmation No.: 1767	
Serial No.:	09/898,687	Examiner: V. Bui	
Filing Date:	July 3, 2001	Group Art Unit: 3731	
Docket No.:	1001.1458	Customer No.: 28075	
For:	CATHETER HAVING VARIABLE WIRE SIZE RADIOPAQUE BRAID		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. §1.8 (1(i)(B))
I hereby certify that this correspondence is being transmitted by facsimile to the United States Patent and Trademark Office at 703-872-9306 on the date shown below.

Kathleen L. Boekley
Type or print name of person signing certification

Kathleen L Boekley — November 8, 2004
Signature — Date

Dear Sir:

Pursuant to 37 C.F.R. § 1.192, Appellants hereby submit this Appeal Brief in furtherance of the Notice of Appeal filed on September 7, 2004. Please charge the fee prescribed by 37 C.F.R. § 1.17(c) in the amount of $340.00 to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit deposit account number 50-0413 for any errors in fee calculation.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Maple Grove, Minnesota 55311. An assignment from the inventor, Henry J. Pepin, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 011972, Frame 0018.

II. RELATED APPEALS AND INTERFERENCES

Neither Appellant, Appellant's legal representatives, nor assignee know of any other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-2, 5-15 and 19-24 stand finally rejected under 35 U.S.C. §103(a) as unpatentable over Steen et al. (U.S. Patent No. 6,213,995).

Claims 16-18 stand finally rejected under 35 U.S.C. §103(a) as unpatentable over Steen et al. (U.S. Patent No. 6,213,995), in view of Sater et al. (U.S. Patent No. 6,068,622).

Claims 3 and 19-21 have been cancelled without prejudice.

Appellant hereby appeals the final rejection of all pending claims 1-2, 4-18 and 22-24.

IV. STATUS OF AMENDMENTS

All Amendments appear to have been entered. An After-Final Amendment to correct a claim dependency is filed herewith.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention is directed to an intravascular catheter having a reinforced elongate shaft that combines high strength and high radiopacity in an interwoven braid (please see, for example, the specification at page 1, lines 16-19). The high strength wires provide torque, column strength and burst strength to the shaft, while the highly radiopaque wires provide enhanced radiopacity (please see, for example, the specification at page 1, lines 19-22).

Turning now to the claims, claim 1 describes an intravascular catheter (Figure 1, reference 10) having an elongate shaft (Figure 1, reference 30) that has a proximal end, a distal end (please see, for example, the specification at page 2, line 22) and a lumen (Figures 2 and 4, reference 44) that extends therethrough. The shaft (Figure 1, reference 30) includes an inner layer (Figure 2, reference 54), an outer layer (Figure 2, reference 52) and a reinforcement layer (Figures 2 and 3, reference 50) that is disposed between the inner layer and the outer layer.

It should be noted that in the specification, reference number 56 in Figure 3 has been used to refer to the first wire, which is described in the specification as the relatively smaller, highly radiopaque wire such as tungsten, while reference number 58 in Figure 3 has been used to refer to the second wire, which is described in the specification as the relatively larger, high strength wire such as stainless steel.

It is important to note that use of "first" and "second" to define relative elements are arbitrary, as the pending claims define the first wire as being the larger diameter, high strength wire and the second wire as the smaller diameter, highly radiopaque wire. Thus, for purposes of this Appeal, and for reference herein, Appellant will use the reference number 58 to refer to the first wire (the high strength wire such as stainless steel) and the reference number 56 to refer to

the second wire (the highly radiopaque wire such as tungsten). Thus, the references made herein are consistent with the claimed invention.

The reinforcement layer (Figures 2 and 3, reference 50) includes a first wire (Figure 3, reference 58) that is wound in a first direction and a second, highly radiopaque, wire (Figure 3, reference 56) formed of tungsten that is wound in a second direction that is different from the first direction (please see, for example, the specification at page 5, lines 13-22). The first wire (Figure 3, reference 58) is interwoven with the second wire (Figure 3, reference 56) (please see Figure 3). The first wire (Figure 3, reference 58) has a first diameter and the second wire (Figure 3, reference 56) has a second diameter that is less than the first diameter.

Claim 2, which depends from claim 1, further recites that the first wire (Figure 3, reference 58) includes a stainless steel wire to provide strength to the shaft (Figure 1, reference 30) (please see, for example, the specification at page 5, lines 21-22).

Claim 4, which has been amended to depend from claim 1, further recites that the reinforcement layer (Figures 2 and 3, reference 50) also includes a third wire (Figure 3, reference 58) that runs parallel and adjacent to the first wire (Figure 3, reference 58) (please see, for example, the specification at page 5, line 15, with respect to first wire 58 including a pair of wires).

Claim 5, which depends from claim 4, further recites that the third wire (Figure 3, reference 58) has a diameter that is equal to the diameter of the first wire (Figure 3, reference 5) (please see, for example, the specification at page 5, lines 13-22).

Claim 6, which depends from claim 5, further recites that the reinforcement layer (Figures 2 and 3, reference 50) also includes a fourth wire (Figure 3, reference 56) that runs

parallel and adjacent to the second wire (Figure 3, reference 56) (please see, for example, the specification at page 5, line 14, with respect to second wire 56 including a pair of wires).

Claim 7, which depends from claim 6, further recites that the fourth wire (Figure 3, reference 56) has a diameter that is equal to the diameter of the second wire (Figure 3, reference 56) (please see, for example, the specification at page 5, lines 13-22).

Claim 8 is an independent claim reciting an intravascular catheter (Figure 1, reference 10) that includes an elongate shaft (Figure 1, reference 30) having a proximal end, a distal end (please see, for example, the specification at page 2, line 23) and a lumen (Figures 2 and 4, reference 44) extending therethrough. The elongate shaft (Figure 1, reference 30) includes an inner layer (Figure 2, reference 54), an outer layer (Figure 2, reference 52), and a reinforcement layer (Figures 2 and 3, reference 50) that is disposed between the inner layer (Figure 2, reference 54) and the outer layer (Figure 2, reference 52).

The reinforcement layer (Figures 2 and 3, reference 50) includes a first wire (Figure 3, reference 58) that is wound in a first direction and a second wire (Figure 3, reference 56) that is wound in a second direction that is different than the first direction (please see, for example, the specification at page 5, lines 13-22). The first wire (figure 3, reference 58) is interwoven with the second wire (Figure 3, reference 56) (please see Figure 3). The first wire (Figure 3, reference 58) includes stainless steel and the second wire (Figure 3, reference 56) includes a highly radiopaque material including tungsten (please see, for example, the specification at page 5, lines 13-22).

Claim 9, which depends from claim 8, further recites that the first wire (Figure 3, reference 58) has a first diameter and that the second wire (Figure 3, reference 56) has a second

diameter that is less than the first diameter (please see, for example, the specification at page 5, lines 17-19).

Claim 10, which depends from claim 8, further recites that the reinforcement layer (Figures 2 and 3, reference 50) further includes a third wire (Figure 3, reference 58) that runs parallel and adjacent the first wire (Figure 3, reference 58) (please see, for example, the specification at page 5, line 15, with respect to first wire 58 including a pair of wires).

Claim 11, which depends from claim 10, further recites that the third wire (Figure 3, reference 58) has a diameter that is equal to the diameter of the first wire (Figure 3, reference 58) (please see, for example, the specification at page 5, lines 13-22).

Claim 12, which depends from claim 10, further recites that the reinforcement layer (Figures 2 and 3, reference 50) further includes a fourth wire (Figure 3, reference 56) that runs parallel and adjacent to the second wire (Figure 3, reference 56) (please see, for example, the specification at page 5, line 14, with respect to second wire 56 including a pair of wires).

Claim 13, which depends from claim 12, further recites that the fourth wire (Figure 3, reference 56) has a diameter that is equal to the diameter of the second wire (Figure 3, reference 56) (please see, for example, the specification at page 5, lines 13-22).

Claim 14 is an independent claim reciting an intravascular catheter (Figure 1, reference 10) that includes an elongate shaft (Figure 1, reference 30) having a proximal end, a distal end (please see, for example, the specification at page 2, line 23) and a lumen (Figures 2 and 4, reference 44) that extends therethrough. The shaft (Figure 1, reference 30) includes an inner layer (Figure 2, reference 54), an outer layer (Figure 2, reference 52), and a reinforcement layer (Figures 2 and 3, reference 50) that is disposed between the inner layer (Figure 2, reference 54) and the outer layer (Figure 2, reference 52).

The reinforcement layer (Figures 2 and 3, reference 50) includes a first pair of wires (Figure 3, reference number 58) that are wound in a first direction and a second pair of wires (Figure 3, reference number 56) that are wound in a second direction that is different than the first direction. The first pair of wires (Figure 3, reference 58) are interwoven with the second pair of wires (Figure 3, reference 56) (please see for example Figure 3). The first pair of wires (Figure 3, reference 58) include stainless steel wires having a first diameter, the second pair of wires (Figure 3, reference 56) include highly radiopaque tungsten wires having a second diameter that is less than the first diameter (please see, for example, the specification at page 5, lines 13-22).

Claim 15, which depends from claim 14, further recites that the elongate shaft (Figure 1, reference 30) is sized to navigate vascular pathways (please see, for example, the specification at page 2, lines 14-21, referring to an intravascular catheter (Figure 1, reference 10), as well as originally filed claim 15).

Claim 16, which depends from claim 15, further recites that the outer layer (Figure 2, reference 52) includes multiple sections of distally decreasing stiffness (Figure 1, references 32, 34, 36 and 38, as well as, for example, the specification at page 3, lines 9-15).

Claim 17, which depends from claim 16, further recites that the shaft (Figure 1, reference 30) includes a distal tip (Figure 1, reference 40) having a proximal portion and a distal portion (please see, for example, the specification at page 3, lines 19-20, referencing distal and proximal portions of the distal tip). The distal portion of the tip (Figures 1 and 4, reference 40) includes a flexible polymer without the inner layer or the reinforcement layer (please see, for example, Figure 4, which shows only a single polymer layer, as well as originally filed claim 17).

Claim 18, which depends from claim 17, further recites that the flexible polymer of the distal portion of the distal tip (Figures 1 and 4, reference 40) is readily bondable to the outer layer (Figure 2, reference 52)(please see, for example, originally filed claim 18).

Claim 22 is an independent claim reciting an intravascular catheter (Figure 1, reference 10) that includes an elongate shaft (Figure 1, reference 30) having an inner layer (Figure 2, reference 54), an outer layer (Figure 2, reference 52), and a reinforcement layer (Figures 2 and 3, reference 50) that is disposed between the inner layer (Figure 2, reference 54) and the outer layer (Figure 2, reference 52). The reinforcement layer (Figures 2 and 3, reference 50) has a first wire (Figure 3, reference 58) including stainless steel that is wound in a first direction and a second wire (Figure 3, reference 56) including tungsten that is wound in a second direction. The first and second wires (Figure 3, references 58 and 56) are interwoven together (please see, for example, Figure 3). The first wire (Figure 3, reference 58) has a first diameter and the second wire (Figure 3, reference 56) has a second diameter that is smaller than the first diameter (please see, for example, the specification at page 5, lines 13-22).

Claim 23, which depends from claim 22, further recites that the elongate shaft (Figure 1, reference 30) has a proximal end, a distal end (please see, for example, the specification at page 2, line 23), and a lumen (Figures 2 and 4, reference 44) extending therethrough and defining a wall having an thickness, wherein the second wire (Figure 3, reference 56) is sized to avoid compromising the thickness of the wall (please see, for example, the specification at page 6, lines 1-9).

Claim 24, which depends from claim 22, further recites that the first wire (Figure 3, reference 58) provides torsional rigidity, column strength and burst strength to the catheter shaft,

and the second wire (Figure 3, reference 56) provides highly radiopaque visualization of the catheter shaft (please see, for example, the specification at page 1, lines 19-22).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 1-2, 5-15 and 19-24 are patentable over the § 103(a) rejection relying on Steen et al. (U.S. Patent No. 6,213,995).

2. Whether claims 16-18 are patentable over the § 103(a) rejection relying on Steen et al. (U.S. Patent No. 6,213,995) in view of Sater et al. (U.S. Patent No. 6,068,622).

VII. ARGUMENT

A. Claims 1-2, 5-15 and 19-24 are patentable over the § 103(a) rejection relying on Steen et al. (U.S. Patent No. 6,213,995)

Steen et al. are directed to forming braided flexible tubing that includes signal transmitting elements. These signal transmitting elements may be electrically conductive wires or optical fibers. If the signal transmitting elements are chosen to be electrically conductive wires, Steen et al. disclose a number of metals from which these signal transmitting elements may be formed. In particular, Steen et al. list copper, a variety of copper alloys and coated coppers, aluminum, silver, gold, platinum or rhodium. None of these are tungsten, and thus it is clear that Steen et al. does not disclose the use of tungsten in forming their signal transmitting elements.

The Examiner has argued repeatedly that it would be obvious to substitute tungsten for the platinum taught by Steen et al. This is incorrect for several reasons. First, there is no reason for the Examiner to select platinum as the metal taught by Steen et al. The Examiner is correct in noting that platinum is indeed included in a laundry list of possible metals. However, one of

ordinary skill in the art would recognize that in order to use an electrically conductive wire as the signal transmitting elements taught by Steen et al., one would select a good electrically conductive material. Second, there is no reasonable motivation, absent reconstructive hindsight, to substitute tungsten.

In order to establish a *prima facie* obviousness rejection, all the claim limitations must be taught or suggested by the prior art, there must be a reasonable expectation of success, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine reference teachings. (M.P.E.P. § 2143.01 and § 2145). Appellant will demonstrate that, at a minimum, there is no reasonable motivation to modify the cited reference as suggested by the Examiner.

In forming an electrically conductive wire to serve as a signal transmitting element, one of ordinary skill in the art would be motivated to choose a material that is known to be a good electrical conductor. For example, copper is a well-known, widely-used, electrical conductor. Copper has an electrical conductivity of $0.596 \times 10^6\ \Omega^{-1}\ cm^{-1}$. Silver is another good electrical conductor having an electrical conductivity of $0.630 \times 10^6\ \Omega^{-1}\ cm^{-1}$. Of course, a number of electrically conductive materials exist, and all metals are, by definition, at least somewhat conductive to electricity.

Nonetheless, if one of ordinary skill in the art were to select a metal to form an electrically conductive wire to use as a signal transmitting element, he or she would select a metal that is known as a good electrical conductor. To do otherwise would run counter to that person's education, experience and training. Now, while Steen et al. do indeed disclose platinum, it is not correct to interpret this disclosure as teaching the use of platinum. As noted above, one would choose a good electrical conductor. Platinum is not a good electrical

conductor, having an electrical conductivity of only 0.0966 x 10^6 Ω^{-1} cm^{-1}. It should be noted, by the way, that literature values of electrical conductivity can vary slightly from source to source, as evidenced by the slightly different values provided by the Examiner.

Thus, while Steen et al. do disclose platinum, no one of even ordinary skill in the art would be motivated to choose platinum in order to form electrically conductive wires to use as the signal transmitting elements taught by Steen et al. The Examiner should realize that patent disclosures frequently include laundry lists of possible materials. Such a list cannot necessarily be interpreted as teaching the equivalence of the materials within the list. Rather, a modicum of common sense is required. One of even ordinary skill in the art will read such a disclosure and interpret the disclosure in light of their own experience and expertise.

In the Advisory Action mailed July 30, 2004, the Examiner appears not to understand this basic tenet, as the Examiner asserts that Steen et al., merely by virtue of disclosing this laundry list of metals, teaches that all listed metals are preferred. This is incorrect. Therefore, contrary to the Examiner's assertions, it is not reasonable to interpret Steen et al. as truly teaching the use of platinum in forming electrically conductive wires to use as the signal transmitting elements taught by Steen et al.

As noted above, the Examiner has asserted that it would be obvious to substitute tungsten for the platinum disclosed by Steen et al. Appellants have demonstrated above that while Steen et al. disclose platinum, there can be no reasonable interpretation of Steen et al. that would lead one of even ordinary skill in the art to believe that Steen et al. teach a preferred use of platinum. Thus, the Examiner's basic argument that it would be obvious to substitute tungsten for the platinum allegedly taught by Steen et al. is flawed.

That significant point aside, there are several logical reasons why one of even ordinary skill in the art would not be motivated to make such a substitution. First, tungsten is known to be a relatively poor conductor of electricity, having an electrical conductivity of only $0.189 \times 10^6\ \Omega^{-1}\ cm^{-1}$. While this is, as the Examiner points out, somewhat better than that of platinum, it still means that tungsten is a relatively poor conductor of electricity, particularly when compared to more conventional conductors such as copper. As discussed above, one of even ordinary skill in the art would not choose such a poor conductor.

Second, one of skill in the art would not readily be motivated to use tungsten in forming the signal transmitting elements taught by Steen et al. because tungsten is well-known to be relatively fragile and thus susceptible to breaking. Fragility is an inherent property of tungsten that would be interpreted by one of ordinary skill in the art as arguing against the use of tungsten in forming an electrically conductive wire. Therefore, one of ordinary skill in the art would not choose tungsten because tungsten is a relatively poor conductor of electricity and because tungsten is known to be relatively fragile.

The Examiner has asserted, for example in the Office Action mailed May 5, 2004, that it would be obvious to include tungsten because "it is always desirable for a medical catheter to be radiopaque...". This is not correct. For example, if the catheter itself is completely radiopaque, it will be difficult or impossible to monitor the position of a radiopaque device positioned within the catheter. Moreover, while radiopacity is an issue addressed by the claimed invention, it is an issue foreign to the teachings of Steen et al., as Steen et al. are silent regarding radiopacity. It would appear that the only reasonable suggestion to modify Steen et al. to improve the radiopacity of Steen et al.'s catheter comes from reconstructive hindsight. As noted at M.P.E.P. § 2143 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438), this is improper.

In conclusion, Steen et al. do not disclose a catheter braid that includes tungsten. As demonstrated herein, Steen et al. cannot reasonably be interpreted as suggesting the use of platinum. There is simply no reasonable motivation to substitute tungsten.

As demonstrated herein, one of ordinary skill in the art would have absolutely no motivation, based at least on their own education and experience, to modify the teachings of Steen et al. as suggested by the Examiner. As stated at M.P.E.P. § 2144 (citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596), the motivation to modify a reference must come from either a reference, reliance on scientific principle, common knowledge, or legal precedence.

In the instant rejection, the cited reference is silent as to suggesting the use of tungsten. The Examiner has provided no reference teaching the use of tungsten. While the Examiner has provided Imagaki et al. (U.S. Patent No. 5,630,806) as a rebuttal reference, the reference relies upon stainless steel for radiopacity and thus cannot be considered as teaching the use of tungsten. Therefore, there is no reasonable motivation to modify Steen et al. as suggested by the Examiner.

With respect to scientific principle and common knowledge, Appellant has amply demonstrated that one of ordinary skill in the art, when considering the teachings of Steen et al., would have absolutely no motivation to modify Steen et al. as suggested by the Examiner. Steen et al. is unconcerned with radiopacity. Instead, Steen et al. is concerned with transmitting a signal such as an electrical signal from one end of a catheter to another.

With respect to legal precedent, none is believed to exist. Thus, Appellant asserts that there is no reasonable motivation, absent hindsight, to modify the cited reference as suggested. Therefore, the *prima facie* obviousness rejection is flawed and should be withdrawn. In light thereof, Appellant requests the rejection be reversed.

B. Claims 16-18 are patentable over the § 103(a) rejection relying on Steen et al. (U.S. Patent No. 6,213,995), in view of Sater et al. (U.S. Patent No. 6,068,622)

Steen et al. are distinguished above as failing to suggest a reinforcing braid that includes tungsten. Claims 16-18 depend from, and thereby include all of the limitations of, claim 15, which as argued above is patentable over the teachings of Steen et al. Claims 16-18 are thereby patentable over Steen et al. and moreover add additional patentable limitations. The Examiner has relied upon Sater et al. to suggest particular catheter features not disclosed by Steen et al. However, Sater et al. do not remedy the noted shortcomings of Steen et al. and thus claims 16-18 are patentable over the cited combination. In light thereof, Appellant requests the rejection to be reversed.

C. Conclusion

For at least the reasons stated above, the rejections of claims 1-2 and 4-24 under 35 U.S.C. § 103(a) should be reversed.

Respectfully submitted,

Henry J. Pepin

By his attorney,

Date: 11/8/04

David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349